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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.        |
|---|-------------|----------------------|---------------------|-------------------------|
| 09/880,713  | 06/12/2001  | Ruedi Aebersold      | 39-00               | 5526                    |
| 23713   | 7590        | 08/15/2002           | EXAMINER            |                         |
| GREENLEE WINNER AND SULLIVAN P C<br>5370 MANHATTAN CIRCLE<br>SUITE 201<br>BOULDER, CO 80303 |             |                      | CEPERLEY, MARY      |                         |
| ART UNIT  |             | PAPER NUMBER         |                     |                         |
| 1641  |             | 12                   |                     | DATE MAILED: 08/15/2002 |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                  |
|------------------------------|--------------------------------------|------------------|
| <b>Office Action Summary</b> | Applicant No.                        | Applicant(s)     |
|                              | 09/880,713                           | AEBERSOLD ET AL. |
|                              | Examiner<br>Mary (Molly) E. Ceperley | Art Unit<br>1641 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-73 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_ is/are objected to.

8) Claim(s) 1-73 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

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**1)** Applicants are advised that the language which designates "kits" as being comprised of "groups" or "linkers" renders the claims indefinite under 35 USC 112, second paragraph, for the reason that "groups" and "linkers" do not define discrete components which would be appropriate for a "kit". Rather, the terms "groups" and "linkers" define only incomplete **fragments** of compounds.

**2)** Applicants are advised that claim 62 should apparently be dependent from claim 56 rather than claim 53.

**3)** Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-52 and 68-71, drawn to methods of selectively labeling phosphate groups and methods of detecting phosphopeptides, classified in class 530, subclasses 408-410; class 436, subclasses 501, 544-546; class 435, subclass 188.
- II. Claims 53-63, 72 and 73, drawn to kits comprised of ethanolamine and trifluoroacetic acid and optionally amine protective groups, classified in class 436, subclass 527.
- III. Claim 64, drawn to a kit comprised of ethanolamine, trifluoroacetic acid and a reagent for removing covalently linked phosphopeptides from a solid support, classified in class 435, subclass 975.
- IV. Claim 65, drawn to a kit comprised of ethanolamine, trifluoroacetic acid and a peptide digesting enzyme.
- V. Claim 66, drawn to a kit comprised of a peptide digesting enzyme, a protective group for  $-COOH$  and  $PO_4^{3-}$ , an amine protective group, a phosphoroamide cleaving reagent, and a label with a functional group. (*Note that although claim 66 is dependent from claim 53, it requires different kit components than those recited in claim 53. See also, claim 67.*)
- VI. Claim 67, drawn to a kit comprised of a peptide digesting enzyme, an amine protective group, a reagent for cleaving a phosphoramido bond, one or more linkers, one or more

solid supports, and one or more reagents for cleaving a phosphopeptide from a solid support.

**4)** The inventions are distinct, each from the other because of the following reasons:

**a)** Inventions II-VI are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the various kits may have separate and distinct utilities. For example, the combination of reagents which define the kit of claim 53 could be used to prepare a wide variety of compounds (not limited to peptides) which contain a protected carboxylic acid group. (The "for use in" limitation of step (b) of claim 53 does not limit the composition *per se*, i.e. the composition is comprised ethanolamine and trifluoroacetic acid and may be used *for any purpose*.) See MPEP § 806.05(d). The kit of claim 67, on the other hand, requires a combination of seven components which combination would appear to be useful solely in a method for detecting phosphopeptides. Different patentability considerations are clearly involved among the different kit combinations. For each kit, a patentability determination must be made of the novelty and unobviousness *of the claimed specific combination of individual components independent of any method of use*.

**b)** Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the combination of reagents which define the kit of claim 53 could be used to prepare a wide variety of compounds which contain a protected carboxylic acid group, i.e. the kit is not limited to use in preparing the labeled phosphopeptides of Invention I.

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**5)** Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter requiring divergent fields of search and different patentability considerations, restriction for examination purposes as indicated is proper.

**6)** Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

**6)** Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

**7)** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE** at **(703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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August 14, 2002

*Mary E. Ceperley*

Mary E. (Molly) Ceperley

Primary Examiner

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